

REMARKS

Applicant respectfully requests reconsideration. Claims 1-4, 6, 7, 12-22 and 28-42 were previously pending before entrance of the present Amendment. Claims 1, 20, 28, and 35-38 have been amended. Support for amended claim 1 may be found in the specification, for example, on page 3, lines 13-15; page 4, lines 10-12; and page 5, lines 16-18. Claim 20 has been amended to correct a typographical error. Support for amended claims 28 and 35-38 may be found in original claim 32. Claims 31-34 and 40-42 have been cancelled. Claims 6 and 7 have been allowed. Claims 1-4, 6, 7, 12-22, 28-30, and 35-39 remain pending for examination. No new matter has been added.

Each of the rejections levied by the Examiner in the outstanding Office Action is addressed in turn below.

Rejection under 35 U.S.C. § 112, First Paragraph

Claims 28-31 were rejected under 35 U.S.C. § 112, First Paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Without acceding to the merit of the rejection, and solely to expedite prosecution, claim 28 has been amended to recite “a method of treating a condition selected from schizophrenia, manic episode, severe manic episode, psychosis, or bipolar disorder.” Accordingly, withdrawal of the rejection on this ground is respectfully requested.

Rejection under 35 U.S.C. § 102(b)

Claims 1, 4, 12, 13, 15-22, 28-34 and 37-42 were rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by International Publication No. WO03/007912 (“Dekemper”). Applicant respectfully disagrees.

It is not believed that the Patent Office would be able to show where Dekemper discloses an amorphous form of olanzapine on a commercial scale, wherein the olanzapine comprises less than 10% of crystalline forms of olanzapine and *less than 2% of other impurities*, and wherein the

olanzapine is for use in therapy by oral or parenteral administration, as recited in amended claim 1. By contrast, Dekemper discloses lyophilized or freeze-dried compositions comprising olanzapine intimately mixed with a solubilizer and a stabilizer as essential ingredients. See page 1, lines 10-13; and page 3, lines 22-25, of Dekemper. Dekemper also discloses tartaric acid as a preferred solubilizer and lactose monohydrate as a preferred stabilizer. See page 6, lines 5-8; and page 18, of Dekemper.

Because each limitation is not taught or suggested in Dekemper, claim 1 is patentable over Dekemper. Claims 4, 12, 13, 15-22, 28-30, and 37-38 depend from claim 1 and, thus, are also patentable over Dekemper for at least this reason. Claim 39 is patentable for at least the same reasons as claim 6, which has been allowed by the Examiner. Claims 31-34 and 40-42 have been cancelled. Accordingly, withdrawal of the claim rejections on this ground is respectively requested.

Rejection under 35 U.S.C. § 102(b) or, in the alternative, 35 U.S.C. § 103(a)

Claims 1-4, 12-18, 22-34 and 35-42 were rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by, or, in the alternative, under 35 U.S.C. § 103(a), as allegedly being obvious over International Publication No. WO02/094236 (“Rabinowitz”). Applicant respectfully disagrees.

It is not believed that the Patent Office would be able to show where Rabinowitz discloses an amorphous form of olanzapine *on a commercial scale*, wherein the olanzapine comprises less than 10% of crystalline forms of olanzapine and less than 2% of other impurities, and wherein the olanzapine is *for use in therapy by oral or parenteral administration*, as recited in amended claim 1. By contrast, Rabinowitz discloses the administration of olanzapine in microgram or milligram quantities and in aerosol form. Because each limitation is not taught or suggested in Rabinowitz, claim 1 is patentable over Rabinowitz for at least this reason.

Additionally, those of ordinary skill in the art would not have had reason to modify the teachings of Rabinowitz to produce the invention as claimed. In fact, Rabinowitz teaches away from the invention as claimed in amended claim 1. For example, Rabinowitz solely discloses the use of antipsychotic compositions in small quantities (e.g., microgram or milligram scale), rather than on a commercial scale. In one example, Rabinowitz describes the use of 12.9 mg of olanzapine to form an aerosol. See page 28, paragraph [0166] of Rabinowitz. Moreover, there is no disclosure

in Rabinowitz related to oral or parenteral administration of olanzapine. Rather, in Rabinowitz, aerosols containing antipsychotics (e.g., olanzapine) are administered using devices which form the aerosol immediately prior to administration to a mammal. For example, “the antipsychotic composition volatilizes... and condenses to form a condensation aerosol prior to reaching the mouthpiece 110... the condensation aerosol [is carried] to the mouthpiece 110, where it is inhaled by the mammal.” See page 22, paragraph [0146], of Rabinowitz. Thus, given the differences between the olanzapine compositions, as well as methods of administration, described in Rabinowitz and those claimed in the present application, one of ordinary skill in the art would have had no reasonable expectation of success in modifying the teachings of Rabinowitz to predictably reach the invention as claimed.

Because each claim limitation is not taught or suggested by Rabinowitz, and there is no articulated reasoning as to why one of ordinary skill in the art would modify the teachings of Rabinowitz to predictably reach the invention as claimed, claim 1 is patentable over Rabinowitz. Claims 2-4, 12-18, 22, 28-30, and 35-38 depend from claim 1 and, thus, are also patentable over Rabinowitz. Claim 39 is patentable for at least the same reasons as claim 6, which has been allowed by the Examiner. Claims 23-27 were cancelled in the Office Action Response filed October 8, 2010. Claims 31-34 and 40-42 have been cancelled in the present Amendment. Accordingly, withdrawal of the rejection on these grounds is respectfully requested.

In view of the above amendments and remarks, Applicant believes the pending Application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 23/2825 under Docket No. V0005.70102US00, from which the undersigned is authorized to draw.

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Respectfully submitted,

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